

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re patent application

Appellant: Shlomo Gabbay Art Unit: 3738
Serial No.: 09/973,609 Examiner: B. Pellegrino
Filed: October 9, 2001
Title: IMPLANTATION SYSTEM FOR IMPLANTATION OF A HEART
VALVE PROSTHESIS

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Sir:

Following the Examiner's Answer dated October 9, 2007, Appellant presents this

Reply Brief.

1. STATUS OF CLAIMS

Independent claims 51, 62 and dependent claims 21-28, 52, 61-70, which are submitted herewith in the first Appendix, are currently pending in this Application.

Claims 1-20, 29-50 and 53-60 have been canceled. Claims 21, 28, 51, 61-63, 67 and 70 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,370,685 to Stevens (hereinafter "Stevens"). Claim 52 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,851,210 to Torossian (hereinafter "Torossian"). Claims 22-26, 65, 66, 68 and 69 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stevens in view of U.S. Patent No. 6,077,296 to Shokoohi et al. (hereinafter "Shokoohi"). Claim 27 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,851,210 to Vesely et al. (hereinafter "Vesely"). Claim 64 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,733,267 to Del Toro (hereinafter "Del Toro"). Independent claims 51, 62 and dependent claims 21-28, 52, 61-70 are being appealed.

2. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

a. Whether the rejection of claims 21, 28, 51, 61-63, 67 and 70 under 35 U.S.C.

103(a) as being made obvious by Stevens is proper.

b. Whether the rejection of claim 52 under 35 U.S.C. 103(a) as being made

obvious by Stevens in view Torossian is proper.

c. Whether the rejection of claims 22-26, 65, 66, 68 and 69 under 35 U.S.C.

103(a) as being made obvious by Stevens in view of Shokoohi is proper.

d. Whether the rejection of claim 27 under 35 U.S.C. 103(a) as being made

obvious by Stevens in view Vesely is proper.

e. Whether the rejection of claim 64 under 35 U.S.C. 103(a) as being made

obvious by Stevens in view of Del Toro is proper.

3. ARGUMENTS

Regarding independent claims 51 and 62, the Examiner's Answer contends that the introducer capsule shown and described in U.S. Patent No. 5,370,685 to Stevens (hereinafter, "Stevens") falls within the claimed range of 5 mm to 15 mm because the introducer channel (50) has an internal diameter of about 0.5 to about 10 mm. See Examiner's Answer at page 5, lines 1-4, citing Stevens at Col. 7, lines 65, 66. However, the conclusion that the introducer capsule (the structure disclosed as containing the prosthetic valve device - Stevens at Col. 7, lines 29-32) would be within the recited range in view of the internal diameter of the introducer channel appears to be based on speculation by the Examiner since the Examiner has not identified any evidence to support the allegation. It is well settled that, "Speculation is not sufficient for establishing a prima facie case of obviousness... a rejection based on §103, must rest upon a factual basis rather than conjecture, or speculation." *Ex Parte Yamamoto*, 57 U.S.P.Q.2d 1382, 1383 (B.P.A.I. 2001); citing *In re Warner*, 379 F.2d 1011, 1017, 154 U.S.P.Q. 173, 178 (CCPA 1967). There is no mention in Stevens of a basis to conclude the dimensions of introducer capsule based on the disclosed dimensions of the introducer channel.

Also regarding claims 51 and 62, the Examiner admits that Stevens fails to disclose that a cylindrical member extends to terminate in an opening spaced longitudinally apart from a body portion. Examiner's Answer, last line of page 5, to line 1 of page 6. The Examiner, without the benefit of any teaching from Stevens and without offering any evidence, then concludes that it would have been an obvious expedient to have the cylindrical member terminate apart from the [bracer (70)] such

that it enables the surgeon to deliver the prosthesis to an area that is at a distance from the area where the delivery device can be stabilized for the surgeon to precisely place the implant. Examiner's Answer, page 6, lines 1-5. This conclusion appears contrary to the teachings of Stevens, which expressly states that the bracer (70), which comprises a differentially expandable device, such as a series of segmented balloons, is circumferentially attached to the external surface of the introducer capsule at the capsule's proximal end. Stevens, Col. 7, lines 38-42. The Examiner has offered no evidence to support its finding that one skilled in the art would be able to combine the teachings of a single patent reference of Stevens to form the claimed invention of claims 51 and 62. *In re Lueders*, 111 F.3d 1569, 1571, 42 U.S.P.Q.2D (BNA) 1481, 1482 (Fed. Cir. 1997).

Since no evidence has been presented to modify the bracer (70) of Stevens to as suggested in the Examiner's Answer, such a proposition must be based on pure speculation (*Ex Parte Yamamoto, supra.*), based on improper hindsight (*In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998)) or based on the Examiner's personal knowledge. Thirty-seven C.F.R. §1.04(d)(2) states that:

When a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by an affidavit of such employee, and such affidavit shall be subject to contradiction or explanation by the affidavits of the applicant and other persons.

If the above rejection is maintained, Appellant's representative, requests an affidavit of the Examiner to support the Examiner's statement pursuant to 37 C.F.R. §1.104(d)(2) that moving the bracer (70) to a location that is spaced apart from the opening would be obvious to one of ordinary skill in the art for the reasons set forth in the Examiner's

Answer. Appellant further requests an opportunity to respond to and contradict such an affidavit. Appellant respectfully submits that there is no evidence to support that one of ordinary skill in the art would seek to modify Stevens in the manner suggested in the Examiner's Answer. There further is no evidence of record to support the rationale proffered in the Examiner's Answer that moving the bracer (70) would be beneficial or achieve the results alleged by the Examiner. Therefore, in the absence of an affidavit or other evidence produced by the Examiner, the grounds of rejection under 35 U.S.C. 103(a) is insufficient to conclude that claims 51 and 62 are obvious in view of Stevens.

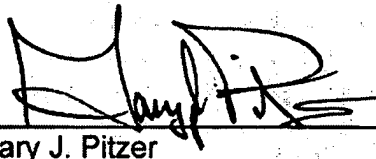
Regarding the grounds of rejection for claim 64, Appellant further notes that valve introducer shown and described in Stevens is part of a catheter that is intended to be transported through the patient's vasculature. Stevens, at Col. 7, lines 29-32. Accordingly, the addition of a handle portion that would extend outwardly from the bracer (70), which comprises inflatable balloons attached to the external surface of the introducer capsule (Stevens, Col. 7, lines 38-40), appears contrary to the express teachings of Stevens. Accordingly, it would not be obvious to use a handle from the teachings of U.S. Patent No. 5,733,267 to Del Toro with the delivery device of Stevens to make the system of claim 64.

The Appellant rests on its arguments to successfully traverse other grounds of rejection.

In the event any fees are due in connection with the filing of this document, including for any extensions of time, the Commissioner is authorized to charge those fees to our Deposit Account No. 20-0090.

Respectfully submitted,

TAROLLI, SUNDHEIM, COVELL & TUMMINO LLP

A handwritten signature in black ink, appearing to read "Gary J. Pitzer", is written over a horizontal line.

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